INTERNATIONAL STANDARD

ISO 80601-2-13

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AMENDMENT 1
2015-03-01

Medical electrical equipment —

Part 2-13:
Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 1

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performances essentielles pour les postes de travail d'anesthésie

AMENDEMENT 1

Reference number
ISO 80601-2-13:2011/Amd.1:2015(E)

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*.

Introduction

The first edition of IEC 80601-2-13 was published in 2011. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012, to update the references to IEC 60601-1-6:2010 to include Amendment 1:2013, to update the references to IEC 60601-1-8:2006 to include Amendment 1:2012 and to update the references to IEC 60601-1-10 to include Amendment 1:2012. This amendment also introduces technical modifications to clarify the relationship between this standard and IEC 60601-2-49 and to further specify ACCESSORIES. It amends requirements on the following aspects, in part due to the publication of the before-mentioned amendments:

— addition of a definition on INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— marking the mass of MOBILE ME EQUIPMENT;

— movement over a threshold;

— rough handling test;

— MULTIPLE SOCKET-OUTLETS;

— specific requirements on ANAESTHETIC GAS DELIVERY SYSTEMS and ANAESTHETIC BREATHING SYSTEMS including instructions for use;

— vapour concentration during and after oxygen flush;

— inspiratory pause.

Where appropriate, this amendment also includes modifications of specific informative annexes related to the amended requirements as listed above. Finally, minor editorial updates were made.

Medical electrical equipment —

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

AMENDMENT 1

201.1 Scope, object and related standards

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.1.4 * Particular standards

Replace IEC 60601-1:2005 by IEC 60601-1:2005+A1:2012.

Add the following paragraph at the end of this subclause:

If an ANAESTHETIC WORKSTATION is supplied with physiological monitoring, having more than one APPLIED PART on the PATIENT, then IEC 60601-2-49 applies. Measured parameters related to the inherent function of an ANAESTHETIC WORKSTATION (i.e. airway pressure, ventilation volume, oxygen concentration, volatile anaesthetic agent concentration, CO_2/N_2O), including derived and related parameters such as spontaneous ventilation volume or CO_2 production, are not considered to be a PHYSIOLOGICAL MONITORING UNIT as per IEC 60601-2-49.

201.2 Normative references

In the existing introductory paragraph, replace the first sentence with:

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application.

Add the following reference:

IEC 60601-2-49:2011, *Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment*

Amend the following existing references:

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

+Amendment 1:2012

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

+Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

+Amendment 1:2012

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral standard: Requirements for the development of physiologic closed-loop controllers*

+Amendment 1:2012

201.3 Terms and definitions

Replace the introductory sentence by the following sentence:

For the purposes of this document, the terms and definitions given in ISO 4135:2001, IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2007, IEC 60601-1-6:2010+A1:2013, IEC 60601-1-8:2006+A1:2012 and the following apply.

Add the following new term and definition:

201.3.240

*** INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM**

ANAESTHETIC VAPOUR DELIVERY SYSTEM that

— by design is intended to be used with different ANAESTHETIC WORKSTATIONS, and

— can be exchanged by the clinical user without the use of tools and without the need for specific tests

201.4 General requirements

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

In the second column, fourth line, replace "reserve flow" by "reverse flow".

201.5 General requirements for testing ME EQUIPMENT

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.7 ME EQUIPMENT identification, marking and documents

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

Add the following subclause:

201.7.2.21 * Mass of MOBILE EQUIPMENT

Replacement:

The ANAESTHETIC WORKSTATION shall be legibly marked with its maximum mass in kilograms [see also 201.101.1.1 k)].

201.7.2.106 * Marking with mass

Delete this subclause completely.

201.7.9.3.101 Components

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.9.4 Instability HAZARDS

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.9.4.2.4.3 Movement over a threshold

Replace the text by the following text:

Amendment:

ANAESTHETIC WORKSTATIONS that are intended only to be used when mounted to a wall or pendant, but may need to be removed from the wall or pendant for service or at initial installation, are not considered MOBILE EQUIPMENT and the threshold test specified in IEC 60601-1:2005+A1:2012, 9.4.2.4.3 does not apply. Such non-MOBILE machines can use small casters to aid service and installation of the device. See also 201.7.9.3.102.

The first paragraph

("In the requirement replace the height of the threshold by 10 mm (instead of 20 mm) and in the test method replace the height of the solid vertical plane obstruction by 10 mm (instead of 20 mm.")

is deleted.

201.10 Protection against unwanted and excessive radiation HAZARDS

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.11 Protection against excessive temperatures and other HAZARDS

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.12.4.102 * Additional requirements for ANAESTHETIC WORKSTATIONS

Correct the reference in the 9th list item and correct the corresponding text in Table 201.C.103 (ACCOMPANYING DOCUMENTS, general) to read:

— ANAESTHETIC BREATHING SYSTEM continuing-positive-pressure ALARM CONDITION complying with 201.12.4.106;

201.13 HAZARDOUS SITUATIONS and fault conditions

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.15 Construction of ME EQUIPMENT

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

Add the following subclause:

201.15.3.5 Rough handling test

Amend as follows:

For an ANAESTHETIC WORKSTATION with a weight exceeding 125 kg in its NOMINAL configuration and only movable manually, the speed in a) ascending step shock and b) descending step shock shall be reduced from 0,8 m/s to 0,4 m/s.

201.16 ME SYSTEMS

Replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.16.9.2.1 MULTIPLE SOCKET-OUTLET

Replace the existing text by the following:

Delete the second dash of 16.9.2.1 a) and add the following text under the last list item in 16.9.2.1 a):

An ANAESTHETIC WORKSTATION may provide MULTIPLE SOCKET-OUTLETS that can accept standard MAINS PLUGS of the kind specified in IEC/TR 60083.

Addition:

Add the following list item:

ee) The ANAESTHETIC WORKSTATION and each MULTIPLE SOCKET-OUTLET which can accept a standard MAINS PLUG shall be provided with separate fuses or over-current releases as required for a single piece of ME EQUIPMENT in IEC 60601-1:2005+A1:2012, 8.11.5.

These fuses or over-current releases shall be designed such that the ANAESTHETIC WORKSTATION including the MULTIPLE SOCKET-OUTLET maintain normal function with each MULTIPLE SOCKET-OUTLET loaded to the maximum rating.

If any MULTIPLE SOCKET-OUTLET is overloaded by a factor of 7,5 ± 2,5, all remaining MULTIPLE SOCKET-OUTLETS and the ANAESTHETIC WORKSTATION shall maintain normal function.

Check compliance by visual inspection and functional testing.

Replace the 3rd dash of 16.9.2.1 c) by:

— PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6, except that the total impedance of the protective earth path for an ANAESTHETIC WORKSTATION may be up to 400 mΩ, or higher if the conditions of 8.6.4 b) are satisfied.

201.101 Additional requirements for ANAESTHETIC GAS DELIVERY SYSTEMS

201.101.1.1 Instructions for use

Amend this subclause and the corresponding text in Table 201 C.103 (ACCOMPANYING DOCUMENTS, general) as follows:

Amend item g) as follows:

g) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM used with the ANAESTHETIC GAS DELIVERY SYSTEM shall comply with this International Standard;

Add a new list item k):

k) the mass in kilograms (kg) in the NOMINAL configuration and a definition of the NOMINAL configuration. The mass in kilograms (kg) shall be disclosed for each ACCESSORY with a mass exceeding 1,5 kg.

201.101.4.1.4 * Reserve oxygen supply

Amend this subclause as follows:

In addition to a connection for the main oxygen supply, the ANAESTHETIC GAS DELIVERY SYSTEM shall be equipped with means of connection to a reserve (back-up) oxygen supply.

Add a new Subclause 201.101.10:

201.101.10 Interface to INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEMS

For ANAESTHETIC GAS DELIVERY SYSTEMS intended to be used with INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEMS the flow of gas from the oxygen flush shall be delivered to the FRESH-GAS OUTLET without passing through an anaesthetic vapour delivery module.

When the FRESH-GAS OUTLET is open to atmosphere, the pressure at the outlet from the ANAESTHETIC VAPOUR DELIVERY SYSTEM shall not increase by more than 10 kPa above its normal working pressure and not decrease by more than 10 kPa below its normal working pressure when the oxygen flush is operated throughout the RATED range of inlet pressure.

Compliance is checked by functional testing. For test procedures see 201.104.2.2.

201.102.1.2 Instructions for use

Amend this subclause and the corresponding text in Table 201.C.103 (ACCOMPANYING DOCUMENTS, general) as follows:

Amend item l) as follows:

l) for breathing ACCESSORIES intended to be assembled by the OPERATOR, the resistance at 2,5 l/min, 15 l/min and 30 l/min and the compliance of those ACCESSORIES;

add a new item n) as follows:

n) The instructions for use shall disclose the inspiratory and expiratory pressure/flow rate characteristics of the ANAESTHETIC BREATHING SYSTEM, including the pressure at

- — 30 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for adult PATIENTS;
- — 15 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for paediatric PATIENTS;
- — 2,5 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for neonatal PATIENTS;

at a FRESH GAS flow rate of 10 l/min ±1 l/min or the maximum FRESH-GAS INLET flow rate specified in the instructions for use, whichever is greater.

201.102.5.3 * Reservoir bag connection port

Amend this subclause as follows:

The reservoir bag connection port, if provided, shall be

- — compatible with a reservoir bag complying with ISO 5362 and a BREATHING TUBE complying with ISO 5367, or
- — a 22 mm socket complying with ISO 5356-1.

NOTE This amendment to ISO 80601-2-13 deliberately includes two options for the reservoir bag connection port in order to allow for a transition period. It is intended to revise this subclause during the next revision of ISO 80601-2-13 by mandating that the reservoir bag be (exclusively) a 22 mm socket complying with ISO 5356-1.

This connection shall be within 20 ° of the vertical axis.

The reservoir connection port shall not be on the PATIENT side of the inspiratory or expiratory valve(s).

The reservoir bag connection port shall be marked with the word “bag” or the equivalent in a language that is acceptable to the intended OPERATOR, or an appropriate symbol.

Check compliance by inspection, functional testing and application of the tests of ISO 5362, ISO 5367 *and* ISO 5356-1.

201.102.7* Inspiratory and expiratory pressure/flow rate characteristics

Amend the text as follows:

The pressure, either positive or subatmospheric, generated at the PATIENT CONNECTION PORT, in any combination of the ANAESTHETIC BREATHING SYSTEM and ACCESSORIES such as breathing hoses, water traps, microbial filters and Y-PIECES as recommended by the MANUFACTURER, shall not exceed 6 hPa (6 cmH_2O) at the peak flow rate of

— 30 l/min if the ANAESTHETIC BREATHING SYSTEM and the ACCESSORIES are intended for adult PATIENTS;

— 15 l/min, if the ANAESTHETIC BREATHING SYSTEM and the ACCESSORIES are intended for paediatric PATIENTS;

— 2,5 l/min, if the ANAESTHETIC BREATHING SYSTEM and the ACCESSORIES are intended for neonatal PATIENTS;

at a FRESH GAS flow rate of 10 l/min ± 1 l/min or the maximum FRESH-GAS INLET flow rate specified in the instructions for use, whichever is greater.

Check compliance by functional testing of any combination of the ANAESTHETIC BREATHING SYSTEM and ACCESSORIES such as breathing hoses, water traps, microbial filters and Y-PIECES as recommended by the MANUFACTURER under the worst case scenario and inspection of the instructions for use.

201.102.9.2 *Absorbent bypass mechanism

In the last sentence, replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

201.104 Additional requirements for an ANAESTHETIC VAPOUR DELIVERY SYSTEM

Add the following

The following requirements for an ANAESTHETIC VAPOUR DELIVERY SYSTEM apply whether the ANAESTHETIC VAPOUR DELIVERY SYSTEMS are interchangeable systems or not.

201.104.3 * Vapour outlet during and after oxygen flush

Amend the headline and the text of this subclause as follows:

201.104.3 * Vapour concentration during and after oxygen flush

During and after oxygen flush, the anaesthetic vapour concentration delivered by the ANAESTHETIC VAPOUR DELIVERY SYSTEM shall not increase by more than 20 %.

For INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEMS, check compliance with the following test:

a) *Set up the INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM according to 201.104.2.2 a) through e).*

Set the fresh gas flow rate through the INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM to (8 ± 0,8) l/min.

To simulate activation of the O_2 flush, apply a steady pressure at the ANAESTHETIC VAPOUR DELIVERY SYSTEM outlet of (100 ± 5) hPa [(100 ± 5) cmH_2O] for 10 s.

Measure the concentration at the outlet for 1 min before, during the application of the pressure and for 30 s after relief of the pressure.

Repeat this for each of the settings given in Table 201.104.

b) *Set up the INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM according to 201.104.2.2 a) through e).*

To simulate activation of the O_2 flush, apply a steady subatmospheric pressure of 100 hPa (100 cmH_2O) for 10 s.

Measure the concentration at the outlet for 1 min before, during the application of the pressure and for 30 s after relief of the pressure.

Repeat this for each of the settings given in Table 201.104.

For non- INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEMS, check compliance with the following test:

Set up the ANAESTHETIC WORKSTATION according to the instructions for use.

Set the FRESH GAS flow rate to (8 ± 0,8) l/min.

Activate the O_2 flush for 10 s.

Measure the concentration at the FRESH GAS OUTLET for 1 min before, during activation of the O_2 flush and for 30 s after releasing the O_2 flush.

NOTE Concentration values can be filtered with a 5 s moving average for evaluation.

Repeat this for each of the settings given in Table 201.104.

201.105.7.1 Expiratory pause

In list item d) replace IEC 60601-1-8:2006 *by* IEC 60601-1-8:2006+A1:2012.

201.105.7.2 Inspiratory pause

Correct the reference in item b):

b) The high-pressure ALARM CONDITION of 201.12.4.109 and the PROTECTION DEVICE of 201.105.2 shall remain active during an inspiratory pause.

In list item e) replace IEC 60601-1-8:2006 *by* IEC 60601-1-8:2006+A1:2012.

201.106.2 Flow-volume loops

Delete this subclause completely.

208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

Replace IEC 60601-1-8:2006 *by* IEC 60601-1-8:2006+A1:2012.

208.6.12 *ALARM CONDITION logging

Replace the headline of this subclause by:

208.6.12 *ALARM SYSTEM logging

210 PROCESS requirements for the development of physiologic closed-loop controllers

Replace IEC 60601-1-10:2007 *by* IEC 60601-1-10:2007+A1:2012.

Annex C (informative) — Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS or their parts

Table 201.C.101 — Marking on the outside of the ANAESTHETIC WORKSTATION and its individual components

Delete row for subclause **201.7.2.106 * Marking with mass** *and add corresponding row for* **201.7.2.21 * Mass of MOBILE ME EQUIPMENT:**

The ANAESTHETIC WORKSTATION shall be legibly marked with its maximum mass in kilograms [see also 201.101.1.1 k)].

Table 201.C.103 – ACCOMPANYING DOCUMENTS, general

Amend Table 201 C.103 as follows:

Subclause 201.101.1.1

Replace g) by:

g) if the ANAESTHETIC GAS DELIVERY SYSTEM is designed to be equipped with an INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM, a statement to the effect that the INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM used with the ANAESTHETIC GAS DELIVERY SYSTEM shall comply with this International Standard;

Add a new list item k):

k) the mass in kilograms (kg) in the NOMINAL configuration and a definition of the NOMINAL configuration. The mass in kilograms (kg) shall be disclosed for each ACCESSORY with a mass exceeding 1,5 kg.

Subclause 201.102.1.2

Replace item l) by the following text:

l) for breathing ACCESSORIES intended to be assembled by the OPERATOR, the resistance at 2,5 l/min, 15 l/min and 30 l/min and the compliance of those ACCESSORIES;

Add a new item n) as follows:

n) The instructions for use shall disclose the inspiratory and expiratory pressure/flow rate characteristics of the ANAESTHETIC BREATHING SYSTEM, including the pressure at

— 30 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for adult PATIENTS;

— 15 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for paediatric PATIENTS;

— 2,5 l/min if the ANAESTHETIC BREATHING SYSTEM is intended for neonatal PATIENTS;

at a FRESH GAS flow rate of 10 l/min ± 1 l/min or the maximum FRESH-GAS INLET flow rate specified in the instructions for use, whichever is greater.

Delete the row for 201.102.7 because this is covered by the additional entry 201.102.1.2 n).

Table 201.C.104 – Technical description

In the 2nd line, first row of Table 201 C.104, replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

Annex D (informative) — Symbols on marking

In the introductory sentence, replace IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

Annex AA (informative) — Particular guidance and rationale

Add the following new text:

Subclause 201.1.4 Particular standards

IEC 60601-2-49 specifies requirements for multiparameter monitors, i.e. devices that monitor more than one parameter with more than one APPLIED PART (= sensor) on one PATIENT. In detail these are

b) electrical safety of devices with more than one APPLIED PART in contact with the PATIENT;

c) multi-parameter ALARM SYSTEMS;

d) ingress protection (IP class) requirements;

e) electromagnetic compatibility.

Even if this basic definition seems to apply to ANAESTHETIC WORKSTATIONS, all of these aspects are covered by the General Standard. ANAESTHETIC WORKSTATIONS are exempt from the requirements of IEC 60601-2-49 to allow MANUFACTURERS to fully integrate any component considered useful into the ANAESTHETIC WORKSTATION. They are encouraged to develop a consistent user interface for all integrated functions, especially regarding the ALARM SYSTEM. However, the required RISK MANAGEMENT PROCESS has to fully address any RISKS arising from integration of additional components.

Add the following new text:

Subclause 201.3.240 INTERCHANGEABLE ANAESTHETIC VAPOUR DELIVERY SYSTEM

Currently, two designs of anaesthetic vapour delivery devices are known. They are either an integral part of the ANAESTHETIC WORKSTATION and cannot be exchanged by users at all or only between ANAESTHETIC WORKSTATIONS of the same type.

The other, allows the use of a non-integral vaporizer that may be exchanged by the clinician not requiring tools.

Add the following new text:

Subclause 201.7.2.21 Mass of MOBILE ME EQUIPMENT

Modern ANAESTHETIC WORKSTATIONS are quite heavy, especially if fully equipped with various components required in this International Standard and other devices needed for routine clinical use. ANAESTHETIC WORKSTATIONS are usually MOBILE devices that are intended to be moved between operating rooms and taken to maintenance locations by the clinical user or hospital technicians. Marking the device with its mass allows users to select a route more convenient for heavy equipment or to call for assistance to help with the transport.

Subclause 201.7.2.106 Marking with mass

Delete the rationale to this subclause (201.7.2.106) completely.

Subclause 201.102.6 Leakage

Replace the existing text by the following:

The limit of 150 ml/min for an entire ANAESTHETIC BREATHING SYSTEM was established for two reasons:

— to restrict the loss of gas volume intended to be delivered to the PATIENT, and

— to limit ANAESTHETIC GAS pollution in the area of the ANAESTHETIC WORKSTATION.

This limit was considered to be the maximum acceptable in view of all the other potential sources of gas leaks. Today the MANUFACTURER of an ANAESTHETIC WORKSTATION usually provides an integrated ANAESTHETIC BREATHING SYSTEM with the ANAESTHETIC WORKSTATION. Users frequently assemble breathing attachments, such as hoses, water traps, filters, and Y-PIECES, as they need from different MANUFACTURERS. The split of the leakage into 75 ml/min for each the ANAESTHETIC BREATHING SYSTEM and the external ACCESSORIES was introduced to encourage the use of specified combinations that meet at least minimum requirements.

Subclause 201.102.7 Inspiratory and expiratory pressure/flow rate characteristics

Delete the last sentence so that the complete rationale to this subclause reads:

Total expiratory and total inspiratory resistance are established at a maximum of 6 hPa (6 cmH_2O) each in order to limit the work of breathing for the spontaneously breathing PATIENT and to restrict positive end-expiratory pressure. In setting the maximum, the Committee considered the resistances of commercially available components and selected a value between those considered and the ideal of zero resistance. This limit is considered to be the generally acceptable maximum physiological value by clinicians.

Annex DD (informative) — Reference to the essential principles

In Table DD.1, replace all references to IEC 60601-1:2005 *by* IEC 60601-1:2005+A1:2012.

Alphabetized index of defined terms used in this particular standard

Add the new term

INTERCHANGEABLE ANAESTHETIC DELIVERY SYSTEM	201.3.240

Amend the references to the following terms:

ALARM CONDITION	IEC 60601-1-8:2006+A1:2012, 3.1
CLEARLY LEGIBLE	IEC 60601-1:2005+A1:2012, 3.15
ESSENTIAL PERFORMANCE	IEC 60601-1:2005+A1:2012, 3.27
HAZARD	IEC 60601-1:2005+A1:2012, 3.39
HAZARDOUS SITUATION	IEC 60601-1:2005+A1:2012, 3.40
MANUFACTURER	IEC 60601-1:2005+A1:2012, 3.55
MULTIPLE SOCKET-OUTLET	IEC 60601-1:2005+A1:2012, 3.67
NORMAL USE	IEC 60601-1:2005+A1:2012, 3.71
PATIENT	IEC 60601-1:2005+A1:2012, 3.76
PROCEDURE	IEC 60601-1:2005+A1:2012 3.88
PROCESS	IEC 60601-1:2005+A1:2012, 3.89
RISK	IEC 60601-1:2005+A1:2012, 3.102
RISK CONTROL	IEC 60601-1:2005+A1:2012, 3.105
RISK MANAGEMENT	IEC 60601-1:2005+A1:2012, 3.107
RISK MANAGEMENT FILE	IEC 60601-1:2005+A1:2012, 3.108
SINGLE FAULT CONDITION	IEC 60601-1:2005+A1:2012, 3.116
TRANSPORTABLE	IEC 60601-1:2005+A1:2012, 3.130
USABILITY ENGINEERING	IEC 60601-1:2005+A1:2012, 3.137